

REMARKS

This response is in reply to the Final Office Action of October 5, 2005. The Applicant thanks the Examiner for consideration of the remarks in the Response dated June 13, 2005.

Claims 1-13 are currently pending in the application and stand rejected. Claims 1-8, 10, 12 and 13 stand rejected as obvious over WO 98/0093037 to Aneas ("*Aneas*") in view of U.S. Patent Application Publication No. 2002/0072706 to Hiblar ("*Hiblar*") or U.S. Patent Application Publication No. 2003/0093037 to Parker ("*Parker*"). Claim 11 stands rejected over *Aneas* in view of *Hiblar* or *Parker* and further in view of WO 99/53886 to Thibault ("*Thibault*"). Claim 9 stands rejected as obvious over *Aneas* in view of *Hiblar* or *Parker* and further in view of *Manera*. The Final Office Action indicates that these references are combinable because they are in the same area of endeavor. For the reasons set forth below, Applicant respectfully requests that the rejections be reconsidered and withdrawn.

First, Applicant respectfully submits that not all arguments set forth in its Response of June 13, 2005 were addressed, or apparently considered, by the Final Office Action. In particular, the Applicant noted that one reason why the claimed invention was allowable over the references is because one of skill would not look to remedy the deficiencies in *Aneas* with *Hiblar* or *Parker*, to achieve the claimed invention. The claimed invention requires a needle and sleeve device of a non-circular shape that prevents unwanted rotation of the needle. The Office Action agrees that *Aneas* does not teach a needle and sleeve of a non-circular shape. However, more than just not having a non-circular needle and sleeve, *Aneas* would have no use for such a needle and sleeve. This is because *Aneas* already provides a device in which the needle will slide without the possibility of rotation. One of ordinary skill in the art simply would not look to add a non-circular needle and sleeve to render the *Aneas* needle incapable of rotation because the *Aneas* needle already does not rotate. Moreover, even if it were appropriate to combine the references, it is at least as likely that one of skill would remove the noncircular needle and sleeve from *Hiblar* and *Parker* and prevent rotation using *Aneas*'s method. Therefore, even if, as the Final Office Action indicates, the cited references are in the same area of endeavor, it still would not be obvious to one of skill in the art to alter *Aneas* by combining it with *Hiblar* or with *Parker* to achieve the claimed invention.

Also apparently overlooked in the Final Office Action, are Applicant's statements that show that even if there was any motivation to combine *Aneas* and *Parker*, such a combination

would not result in the claimed invention. Neither *Aneas* nor *Parker* teaches, discloses or suggests a non-circular needle. Without any indication of a non-circular needle, the claimed invention quite simply cannot arise by combining *Aneas* and *Parker*. Accordingly, Applicant respectfully requests reconsideration of the rejections on these grounds.

At point 12, the Final Office Action indicates that it would have been a matter of design choice to provide a non-circular cross section, as required by all of the claims of the application. The Office Action indicates that such a “design modification” on the part of the Applicant “does not affect the integrity of the invention.” Applicant respectfully disagrees. As set forth fully in the specification of the application, the claimed invention, and particularly the non-circular cross-section, provides significant advantages. *See, e.g., p. 3, ln. 13-23*. In particular, the claimed invention greatly simplifies the structure of the plunger, and guarantees an adequate positioning of the stop means on the sleeve. Furthermore, the structure simplifies production of the product which results in lower production costs. These advantages demonstrate the importance and patentability of the limitations and claims.

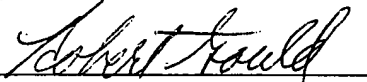
Finally, Applicant reiterates that the cited references are not properly combinable. The Final Office Action indicates that this argument is not persuasive, as *Aneas*, *Hiblar* and *Parker* are “in the same area of endeavor.” Applicant respectfully disagrees and urges reconsideration of the argument. In particular, while each of the references does disclose a device useful in the medical field, these devices are not utilized in the same manner, or by the same artisan. For example, the catheter of *Hiblar* is utilized by highly-skilled practitioners, for a very specific purpose. As discussed previously, these needles are deformable and capable of traversing the circulation system. These devices do not present the same problems and issues as the needles used in reconstitution devices. Reconstitution takes place usually by artisans of more general, laboratory or nursing skills. No special training is required to use the needles in reconstitution devices. Accordingly, the devices of the cited references are not, Applicant respectfully submits, in the same field and are not used for the same endeavor. This renders them unlikely to be combined.

Applicant respectfully requests that the above remarks be fully considered and submits that in view of these circumstances a *prima facie* case of obviousness has not been established and the rejection cannot be maintained. Applicant submits that independent Claims 1, 12 and 13 are allowable and requests that the rejections be withdrawn. In addition, Claims 2-11, which

depend from Claim 1 and therefore contain all of its limitations are allowable for at least the same reasons as Claim 1. Applicant respectfully submits that the application is in condition for allowance and requests that a Notice of Allowance be issued in this case.

Respectfully submitted,

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